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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/179,188	10/27/98	SAKURAI	T KAS-125
			EXAMINER
HM12/0721 FAY SHARPE BEALL FAGAN MINNICH AND MCKEE 104 EAST HUME AVENUE ALEXANDRIA VA 22301			
			PAPER NUMBER
			7

1651
DATE MAILED: 07/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 4/1/99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-13 is/are pending in the application.
- ☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-13 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3 (filed 10/27/98)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The preliminary amendment of 10/27/98 has been entered. The amendment amended claims 9-13.

In a response of 4/28/99 to a restriction requirement of 4/1/99, claims 1-13, of Group I were elected.

5 Claims 14 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 6 of 4/28/99.

Claims examined on the merits are 1-13.

Foreign patent documents have been lined through on page 1 of form
10 PTO-1449 since copies of the documents did not accompany the form.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the accelerator being
guanidine hydrochloride, the solid phase being a material containing
silicon dioxide, the washing solution of claim 1 being that of claim 5,
15 and the washing solution of claim 7 being that of claim 10 or 11, does not reasonably provide enablement for other accelerators, solid phases and washing solutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these
20 claims.

The specification fails to enable accelerators, solid phases and washing solutions other than as set forth above. The art of purifying nucleic acids is unpredictable when different procedures are used, and it cannot be predicted with reasonable certainty as to other accelerators,
25 solid phases and washing solutions that will function like those actually used as described in the specification. The specification provides no

basis and enablement for extrapolating to other accelerators, solid phases and washing solutions.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by failing to set forth clear, distinct and positive process steps. Setting forth the steps as "a step--for" is not a proper way of claiming. This language should be removed from the claims.

10 In line 2 of claims 10 and 11, there is not clear antecedent basis for "said mixture".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to
25 point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al (5,234,809) in view of Seligson et al (4,935,342).

5 Boom et al disclose adsorbing nucleic acids to silicon dioxide containing material (col 2, lines 52-60) in the presence of guanidine hydrochloride (col 3, line 63), washing with a salt containing solution and an alcohol containing solution (col 4, lines 20-30).

Seligson et al disclose adsorbing nucleic acids to an ion exchange column, washing with a chloride salt solution and eluting the nucleic
10 acids (see claims). The salt may be sodium chloride.

It would have been obvious to mix a chloride salt with the ethanol solution used for washing by Boom et al to obtain the function of chloride salt for washing as disclosed by Seligson et al. Using a potassium chloride or acetate salt would have been a matter of obvious
15 choice depending on individual preference and convenience.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00
20 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
25 (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

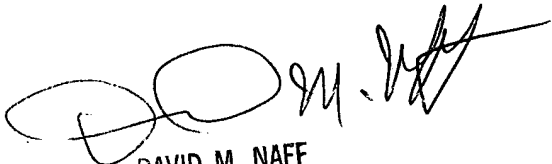
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN
7/18/99


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1285/